

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Wang et al.
Application No.:	10/797996
Filed:	March 11, 2004
For:	Balloon Structure With PTFE Component
Examiner:	Matthew J. Daniels
Group Art Unit:	1791

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Commissioner for Patents
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Docket No.: S63.2Q-7182-US02

REPLY BRIEF ON APPEAL

This is a Reply Brief being filed in response to the Examiner's Answer mailed May 9, 2008. Claims 18 and 23-26 are pending in the application and have been twice or finally rejected.

Reply to Examiner's Answer

The Examiner asserts in the Examiner's Answer dated May 9, 2008, that:

The main issue in this case appears to be whether it would have been obvious to one of ordinary skill in the art to use a high density polyethylene or expanded polytetrafluoroethylene material as the non-distensible bands of Crocker. The non-distensible bands of Crocker et al. are shown as items 40 and 44 in Fig. 2.

Examiner's Answer, page 7, 1st paragraph.

This is not entirely correct.

Applicants submit that the combination of Crocker et al. and Gore fails to disclose or suggest the methods of making a balloon as recited in Applicants' independent claims 18 and 23 whatsoever.

Applicants' independent claim 18 is directed to a method of making a balloon wherein the balloon has at least three layers, the method including providing first, second and third tubes, the second tube formed of a tube made of a material selected from the group consisting of fluoropolymers and high density polyethylene. The first tube is inserted into the second tube, the first and second tubes are inserted into a third tube, and the entire assembly is then placed in a balloon and radially expanded to form the balloon.

The method of independent claim 23 recites a method of forming a balloon including providing first, second and third tubes, inserting the first tube into the second tube, inserting the second tube into the third tube, and laminating the first and second tubes together, and laminating the second and third tubes are laminated together.

Crocker et al. disclose manufacturing a first balloon and a second balloon separately. Expansion limiting bands are positioned at the proximal segment and distal segment of the inner balloon and the outer balloon is then mounted to the catheter body.

Therefore, the Crocker et al. method of making a balloon is completely different than

Applicants tube-in-tube-in-tube methods:

In one particular method of manufacture, inner balloon 36 and outer balloon 38 are attached to the catheter body 10. The proximal necked end 37 of the inner balloon 36 is heat sealed around the catheter body 12. The distal necked end 39 of the inner balloon 36 is thereafter heat sealed around the distal end 16 of the catheter body 12. In general, the length of the proximal end 37 and the distal end 39 of the inner balloon 36 which is secured to the catheter body 12 is within the range of from about 3 mm to about 10 mm, however the proximal and distal balloon necked ends 37, 39 are as long as necessary to accomplish their functions as a proximal and distal seal.

Expansion limiting bands 40 and 44 are respectively positioned at the proximal segment 26 and the distal segment 28 of the inner balloon 36 and may be bonded or otherwise secured to the inner balloon 36. The outer balloon 38 is thereafter be mounted to the catheter body 12 in a similar manner as the inner balloon 36, following "necking down" of the proximal and distal axial ends of the outer balloon 38 by axial stretching under the application of heat. The outer balloon 38 is advanced axially over the inner balloon 36 and the expansion limiting bands 40 and 44. The outer balloon 38 may thereafter be bonded to the inner balloon 36, and to the expansion limiting bands 40 and 44 by any of a variety of bonding techniques such as solvent bonding, thermal adhesive bonding or by heat sealing also depending on the type of balloon material used. Alternatively, the expansion limiting bands are simply entrapped between the balloons without any bonding or adhesion.

Crocker et al., US 5843116, col. 6, lines 63-67 to col. 7, lines 1-25.

Gore et al. fail to disclose making a medical balloon at all much less the specific methods recited in claim 1.

Therefore, the combination fails to disclose or suggest the methods of making the balloon as recited in Applicants' claims 18 and 23.

Second, neither Crocker et al. nor Gore suggest employing a second tube of high density polyethylene, and the combination fails to provide a basis for substituting the materials disclosed by Gore in the balloons of Crocker et al.

Crocker et al. disclose focalized intraluminal balloons:

... A proximal segment, a central segment and a distal segment on the balloon are inflatable to a first inflated diameter at a first inflation pressure, and the proximal and distal segment expand to a second, greater inflated diameter at a second greater inflation pressure. The central segment of the balloon remains at a diameter which is less than the second diameter, at the second inflation pressure. *In one embodiment, the balloon additionally comprises at least one expansion limiting band on the central segment to limit inflation of the central segment of the balloon. Preferably, the expansion limiting band limits expansion of the central segment to no more than about the first inflated diameter.*

Crocker et al., Summary of the Invention, 1st paragraph.

Expansion limiting bands 40 and 44 or other inflation limiting structures can be provided in any of a variety of ways which will be well-understood by one of skill in the art in view of the disclosure herein. For example, in one embodiment, the bands 40 and 44 each comprise a tubular section of polyester, each having an axial length of about 5 mm, a diameter of about 2.5 mm and a wall thickness of about 0.0003 inches. Other generally nondensifiable materials such as nylon, polyamide, Kevlar fiber, cross-linked polyethylene, polyethylene terephthalate and others, may be utilized to accomplish the expansion-limiting effect.

Crocker et al., col. 5, lines 28-39.

As admitted in the Final Office Action dated July 16, 2007, “Crocker ...[is] silent as to the second tube formed of a tube made of a material selected from the group consisting of fluoropolymers and high density polyethylene.” Final Office Action, page 3.

Crocker et al. do suggest “cross-linked polyethylene”.

However, as discussed in the Appeal Brief dated 2/26/08, “cross-linked polyethylene” is a thermoset material which has been subsequently treated in order to cross-link the polymer material. It is not high density polyethylene of the type recited in Applicants’ independent claims. Evidence of this was submitted with the Appeal Brief dated 2/26/08.

Gore discloses “... a tetrafluoroethylene polymer in a porous form which

has an amorphous content exceeding about 5% and which has a micro-structure characterized by nodes interconnected by fibrils.” Abstract.

Films formed of these materials have higher permeabilities to both gases and liquids than conventional film materials. See col. 4, lines 55-62.

Gore discloses that the materials are useful for shaped articles such as films, tubes, rods, and continuous filaments. Gore is silent as to employing the materials in the manufacture of radially expandable medical balloons.

Crocker et al. is silent as to forming the expansion limiting bands from polytetrafluoroethylene (PTFE), much less an expanded PTFE of the type disclosed by Gore wherein the polymer has porous, node and fibril structure and has high permeabilities to gas and liquids. In fact, Crocker et al. disclose that cross-linked stocked tubing can be blown in a Teflon (i.e. PTFE) capture tube (see, for example, col. 6, lines 38-51), making it quite clear that PTFE was not contemplated for use in making the expansion limiting bands 40, 44.

Therefore, there is no *prima facie* case of obviousness.

It is stated in the Examiner’s Answer, that:

Appellants do not appear to have presented any evidence that modifications necessary to achieve the combination were uniquely challenging or difficult for those in the art, or that they produced any unexpected benefits. Thus, once the background for determining obviousness under 35 U.S.C. §103(a) was established by applying the factual inquiries set forth in *Graham v. John Deere Co.*, and it is was determined that the difference between the prior art and the claims at issue was no more than the simple substitution of one known material for another, no further analysis should have been required. *Ex. Parte Smith*, 83 USPQ2d 1509, 1518 (Bd. Pat. App. & Int. 2007) (citing *K.S.R v. Teleflex*). However, even if a TSM type rationale were required, it is submitted that Crocker’s suggestion to use any of a list of materials “and others” (col. 5, ll. 35-39) would additionally motivate one to make the combination set forth in the rejection above.

Examiner's Answer, page 11.

This is incorrect.

Appellants are not required to present any evidence such as unexpected results unless a *prima facie* case of obviousness has been established. It has not.

The proper way in which an obviousness determination is made can be found in MPEP 2142:

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness ... The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to suggest the claimed invention.

To reach a proper determination under 35 U.S.C. §103 the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

MPEP 2142

Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007).

Thus, no *prima facie* case of obviousness has been established because the combination fails to disclose or suggest all of the elements of independent claims 18 and 23, and Applicants therefore do not need to present a showing of unexpected results nor any other objective evidence of nonobviousness.

Furthermore, notwithstanding *KSR*'s treatment of the TSM test, it is simply incorrect to state that "Crocker's suggestion to use any of a list of materials "and others" (col. 5, II.. 35-39) would additionally motivate one to make the combination set forth in the rejection above." The list of materials specifically disclosed by Crocker et al. does not motivate an infinite variety of materials, nor can it be concluded that the Crocker et al. statement, motivates any combination of references. It simply does not. Unless one views the references with impermissible hindsight afforded by the present application, Gore's porous materials, permeable to gases and liquids, are simply not motivated by Crocker et al.'s list of materials. Hindsight bias is still impermissible, even after *KSR*. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d at 1390, 1397 (2007).

Reversal of the rejection of claims 18 and 23-26 is respectfully requested.

Respectfully submitted,

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